UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS

DONNA E. BUMPUS, as Executor of the Estate of LENORA E. BUMPUS,

Plaintiff,

vs.

ETHEX CORPORATION

Defendant,

Serve: C T CORPORATION SYSTEM
120 South Central Ave
Clayton MO 63105

Case No. 10-488-MJR

COMPLAINT

COMES NOW Plaintiff, Donna E. Bumpus, as Executor of the Estate of Lenora E. Bumpus, and for her Complaint against Ethex Inc., states as follows

Introduction

1. This case stems from the wrongful death of Lenora Bumpus, who died on September 21, 2008, as a proximate result of an overdose of isosorbide mononitrate manufactured and sold by Ethex Corporation. It is brought pursuant to the Illinois Wrongful Death Act, 740 ILCS 180.01 et seq., and the Illinois Survival Statute, 755 ILCS 5/27-6.

2. In November of 2008, Ethex issued a voluntary recall of its isosorbide mononitrate tablets. A notice of an "Urgent Product Recall" was sent to Lenora Bumpus (then deceased) around that time, via Walmart, her pharmacy, recalling the product on the

basis that the tablets were oversized, "which could result in [her] taking as much as about two times the expected dosage of the drug."

3. Lenora presented to the hospital on September 4, 2008 and endured significant pain and suffering prior to her death on September 21, 2008. She is survived by two children, Darlene Peterson and Donna Bumpus, who have sustained damage as a result of her passing in the form of the loss of her love, advice, companionship and support, in addition to other damage.

Parties, Jurisdiction And Venue

4. At all relevant times herein, decedent Lenora E. Bumpus was a citizen and resident of Columbia, Illinois. She passed away on September 21, 2008.

5. On or about May 27, 2009, Donna Bumpus was appointed as Executor of the Estate of Lenora Bumpus by the Circuit Court of Monroe County, Illinois. Pursuant to 28 U.S.C. § 1332(c)(2), she is a citizen of the State of Illinois, i.e., the state of the Decedent.

6. Lenora Bumpus is survived by two children, Darlene Peterson and Donna Bumpus. Her husband, Dallas M. Bumpus and her son, Donald Peterson, predeceased her.

7. Defendant Ethex Corporation is, and was at all relevant times, a Missouri corporation with its principal place of business in Missouri engaged in the manufacture, production, design, sale and distribution of pharmaceutical products, including but not limited to isosorbide mononitrate tablets. Upon information and belief, Defendant sell its products nationwide, including the retailers and wholesalers in this District, and has

injected its products into the stream of commerce with the knowledge and expectation that they will be used by consumers in Monroe County, Illinois and this District.

8. Jurisdiction is properly vested in this Court pursuant to 28 U.S.C. § 1332(a)(1), as the matter is between citizens of different states, and the amount in controversy exceeds $75,000, exclusive of interests and costs.

9. Venue is properly vested in this District pursuant to 28 U.S.C. § 1391(a)(2) in that Decedent lived in this District, purchased the drugs at issue in this District, and sustained damages in this District. Venue is also proper pursuant to 28 U.S.C. § 1391(a)(3) on the basis that, by virtue of its extensive sales of products within this District, and placement of its products into the stream of commerce with the knowledge and expectation that they will be used by consumers in this District, Defendant is subject to personal jurisdiction in this district.

Allegations Common To All Counts

10. At some point prior to May 22, 2008, Defendant manufactured and sold particular lots of isosorbide mononitrate, including the following lots (the "Affected Lots"):

a Isosorbide Mononitrate Extended Release Tablets, 30 mg: Lots: 62355, 66423, and 68102 with expiration dates ranging from 11/2008 to 8/2009

b Isosorbide Mononitrate Extended Release Tablets, 60 mg: Lots: 63466, 66034, 67351, and 67354 with expiration dates ranging from 12/2008 to 11/2009

11. At some point after May 22, 2008, Decedent Lenora Bumpus filled a prescription for isosorbide mononitrate extended release tablets, at the Wal-Mart Pharmacy in Waterloo, Illinois, and was provided isosorbide mononitrate tablets from one or more of the Affected Lots.

12. Decedent took the isosorbide mononitrate tablets from one or more of the Affected Lots as prescribed, and in a manner that was intended and/or reasonably foreseeable to Defendant.

13. The tablets contained in the Affected Lots which were purchases and taken by Decedent were defective and unreasonably dangerous in that:

a They contained more than the intended levels of the active ingredient;

b They failed to include warnings of the risk of overdosage when used as reasonably anticipated;

c They failed to comply with applicable legal, regulatory, and administrative approval, licensing, and related requirements for isosorbide mononitrate products and all component parts.

d They had not been subjected to adequate and appropriate quality control processes;

e They were otherwise defective and unreasonably dangerous as the evidence may show.

14. On September 21, 2008, in the wake of taking some of Defendant's defective and unreasonably dangerous isosorbide mononitrate tablets, Lenora Bumpus died.

15. In November of 2008, Defendant Ethex issued an "Urgent Product Recall" with respect to its isosorbide mononitrate products (among other products), which was disseminated to the public at large, generally, and Decedent Lenora Bumpus (then deceased), directly and specifically.

COUNT I

Strict Liability – Wrongful Death

COMES NOW Plaintiff Donna E. Bumpus, as Executor of the Estate of Lenora E. Bumpus, and for Count I of Plaintiff's Complaint against Defendant Ethex, states and alleges as follows:

16. Plaintiff incorporates by reference each and every paragraph prior and subsequent hereto as if fully set forth herein and further alleges on information and belief as follows.

17. At all times relevant to this action, Defendant was the manufacturers and/or suppliers of the Affected Lots, placing the prescription drug into the stream of commerce.

18. The Affected Lots were expected to and did reach Decedent without substantial change in the condition in which they were manufactured and sold.

19. The Affected Lots were defectively manufactured at the time that they left Defendant's control.

20. The Affected Lots were unsafe for normal or reasonably anticipated use.

21. The Affected Lots were unreasonably dangerous in that they were unsafe when used for the intended purpose for medical treatments.

22. The Affected Lots were more dangerous than an ordinary consumer would expect, and the foreseeable risk or injuries from their administration exceeded their associated benefits.

23. Defendant wrongfully permitted defective pharmaceuticals to be placed into the stream of commerce, in the following ways:

a Defendant failed to exercise reasonable care in the manufacture of its isosorbide mononitrate products and/or their pharmaceutical ingredients;

b Defendant failed to exercise reasonable care in the inspection of its isosorbide mononitrate products and/or their pharmaceutical ingredients;

c Defendant failed to exercise reasonable care in the packaging of its isosorbide mononitrate products and/or their pharmaceutical ingredients;

d Defendant failed to provide any or adequate warnings about the risks and dangers associated with the use of its isosorbide mononitrate products, as alleged herein and/or their pharmaceutical ingredients;

e Defendant failed to completely, accurately and in a timely fashion, disclose the adverse event reports associated with the use of its isosorbide mononitrate products and/or their pharmaceutical ingredients;

f Defendant failed to recall, withdraw, and remove its isosorbide mononitrate products and/or their pharmaceutical ingredients from the market as soon as they knew or should have known of the risks and dangers associated with the use thereof;

g Defendant failed to promptly respond to data, reports, and publications describing problems associated with its isosorbide mononitrate products and/or their pharmaceutical ingredients by conducting adequate analysis, testing, and surveillance;

h Defendant failed to implement pre-marketing and post-marketing measures to notify and warn Decedent as well as her physicians, medical providers, and other members of the medical community, of the risks and dangers associated with the use of the said isosorbide mononitrate products and/or their pharmaceutical ingredients, and to recall the defective its isosorbide mononitrate products at the earliest possible opportunity;

i Defendant failed to adequately and reasonably establish, maintain, and comport with acceptable quality control mechanisms to prevent defective products from entering the marketplace;

j Defendant failed to comply with and conform to all applicable legal, regulatory, and administrative approval, licensing, and related requirements for its isosorbide mononitrate products and all component parts.

24. Decedent could not, through the exercise of reasonable care, have discovered the defects or perceived the dangers posed by the drug.

25. Defendant's release of the defective and unreasonably dangerous product, and Decedent's use thereof, caused substantial harm to Decedent, ultimately causing or contributing to cause her death on September 21, 2008.

26. As a direct and proximate result of the death of Lenora Bumpus, the Decedent's next of kin have suffered great losses of a personal and pecuniary nature, including loss of society, loss of consortium, loss of companionship and loss of instruction, training, advice, education and guidance, and other damages for which Defendant are liable, thus subjecting Defendant to liability under 740 ILCS 180/01, commonly referred to as the Illinois Wrongful Death Act.

PLAINTIFF DEMANDS TRIAL BY JURY ON COUNT I.

WHEREFORE, Plaintiff prays this Court enter judgment on Count I in her favor in an amount fair and reasonable to compensate the next of kin for their loss as determined by a jury in an amount to be determined at trial in excess of $75,000, for taxable costs, post-judgment interest, and such other and further relief as this Court deems just and proper under the circumstances.

COUNT II

Strict Liability – Survival Statute

COMES NOW Plaintiff Donna E. Bumpus, as Executor of the Estate of Lenora E. Bumpus, and for Count II of Plaintiffs' Complaint against Defendant Ethex, states and allege as follows:

27. Plaintiff incorporates by reference each and every paragraph prior and subsequent hereto as if fully set forth herein and further alleges on information and belief as follows.

28. As a direct and proximate result of Defendant wrongfully permitting a defective pharmaceutical product to be placed into the stream of commerce as described in more detail herein, and Decedent's use thereof, Decedent Lenora Bumpus suffered serious injuries of a personal and pecuniary nature, including but not limited to, great pain and suffering prior to her death and medical expenses, subjecting the Defendant to liability pursuant to 755 ILCS 5/27-6, commonly referred to as the Illinois Survival Statute.

PLAINTIFF DEMANDS TRIAL BY JURY ON COUNT II.

WHEREFORE, Plaintiff Donna E. Bumpus, as Executor of the Estate of Lenora E. Bumpus, prays this Court enter judgment on Count II in her favor in an amount fair and reasonable to compensate her for her loss as determined by a jury in an amount to be determined at trial in excess of $75,000, for taxable costs, post-judgment interest, and such other and further relief as this Court deems just and proper under the circumstances.

COUNT III

Negligence – Wrongful Death

COMES NOW Plaintiff Donna E. Bumpus, as Executor of the Estate of Lenora E. Bumpus, and for Count III of Plaintiff's Complaint against Defendant Ethex, states and allege as follows:

29. Plaintiff incorporates by reference each and every paragraph prior and subsequent hereto as if fully set forth herein and further alleges on information and belief as follows.

30. Defendant owed a duty to exercise reasonable care in the design, manufacture, testing, marketing, distributing, sale, and/or post-sale surveillance of its isosorbide mononitrate products and their pharmaceutical ingredients, including the dosage given to Decedent, so that they could be safely used for the purpose for which they were intended, or in a reasonable foreseeable manner.

31. This duty included the duty not to introduce a dangerous and unfit pharmaceutical drug into the stream of commerce that caused users to suffer from unreasonable, dangerous or untoward adverse side effects, up to and including death.

32. In breach of its duty of care, Defendant was negligent in the manufacture, testing, distribution, marketing, sale, and/or post-sale surveillance of its isosorbide mononitrate products, including in the following ways:

a Defendant failed to exercise reasonable care in the manufacture of its isosorbide mononitrate products and/or their pharmaceutical ingredients;

b Defendant failed to exercise reasonable care in the inspection of its isosorbide mononitrate products and/or their pharmaceutical ingredients;

c Defendant failed to exercise reasonable care in the packaging of its isosorbide mononitrate products and/or their pharmaceutical ingredients;

d Defendant failed to provide any or adequate warnings about the risks and dangers associated with the use of its isosorbide mononitrate products, as alleged herein and/or their pharmaceutical ingredients;

e Defendant failed to completely, accurately and in a timely fashion, disclose the adverse event reports associated with the use of its isosorbide mononitrate products and/or their pharmaceutical ingredients;

f Defendant failed to recall, withdraw, and remove its isosorbide mononitrate products and/or their pharmaceutical ingredients from the market as soon as they knew or should have known of the risks and dangers associated with the use thereof;

g Defendant failed to promptly respond to data, reports, and publications describing problems associated with its isosorbide mononitrate products and/or their pharmaceutical ingredients by conducting adequate analysis, testing, and surveillance;

h Defendant failed to implement pre-marketing and post-marketing measures to notify and warn Decedent as well as her physicians, medical providers, and other members of the medical community, of the risks and dangers associated with the use of the said isosorbide mononitrate products and/or their pharmaceutical ingredients, and to recall the defective its isosorbide mononitrate products at the earliest possible opportunity;

i Defendant failed to adequately and reasonably establish, maintain, and comport with acceptable quality control mechanisms to prevent defective products from entering the marketplace;

j Defendant failed to comply with and conform to all applicable legal, regulatory, and administrative approval, licensing, and related requirements for its isosorbide mononitrate products and all component parts;

k Defendants were otherwise negligent and careless.

33. Defendant knew or should have known that patients/consumers such as Decedent would foreseeably suffer injury as a result of its failure to exercise ordinary care as described above.

34. Defendant's isosorbide mononitrate products were expected to and did reach Decedent without substantial change in the condition as designed, manufactured, marketed, distributed, and sold, prior to their administration to Decedent who used the isosorbide mononitrate as intended, or in a reasonably foreseeable manner.

35. Defendant's negligent conduct caused substantial harm to Decedent, ultimately causing or contributing to cause her death.

36. As a direct and proximate result of the death of Lenora Bumpus, the Decedent's next of kin have suffered great losses of a personal and pecuniary nature, including loss of society, loss of consortium, loss of companionship and loss of instruction, training, advice, education and guidance, and other damages for which Defendant are liable, thus subjecting Defendant to liability under 740 ILCS 180/01, commonly referred to as the Illinois Wrongful Death Act.

PLAINTIFF DEMANDS TRIAL BY JURY ON COUNT III.

WHEREFORE, Plaintiff prays this Court enter judgment on Count III in her favor in an amount fair and reasonable to compensate the next of kin for their loss as determined by a jury in an amount to be determined at trial in excess of $75,000, for

taxable costs, post-judgment interest, and such other and further relief as this Court deems just and proper under the circumstances.

COUNT IV

Negligence – Survival Statute

COMES NOW Plaintiff Donna E. Bumpus, as Executor of the Estate of Lenora E. Bumpus, and for Count IV of Plaintiffs' Complaint against Defendant Ethex, states and allege as follows:

37. Plaintiff incorporates by reference each and every paragraph prior and subsequent hereto as if fully set forth herein and further alleges on information and belief as follows.

38. As a direct and proximate result of Defendant negligence with respect to its isosorbide mononitrate products as described in more detail herein, and Decedent's use thereof, Decedent Lenora Bumpus suffered serious injuries of a personal and pecuniary nature, including but not limited to, great pain and suffering prior to her death and medical expenses, subjecting the Defendant to liability pursuant to 755 ILCS 5/27-6, commonly referred to as the Illinois Survival Statute.

PLAINTIFFS DEMAND TRIAL BY JURY ON COUNT IV.

WHEREFORE, Plaintiff Donna E. Bumpus, as Executor of the Estate of Lenora E. Bumpus, prays this Court enter judgment on Count IV in her favor in an amount fair and reasonable to compensate her for her loss as determined by a jury in an amount to be determined at trial in excess of $75,000, for taxable costs, post-judgment interest, and such other and further relief as this Court deems just and proper under the circumstances.

COUNT III

Negligence Per Se – Wrongful Death

COMES NOW Plaintiff Donna E. Bumpus, as Executor of the Estate of Lenora E. Bumpus, and for Count III of Plaintiff's Complaint against Defendant Ethex, states and allege as follows:

39. Plaintiff incorporates by reference each and every paragraph prior and subsequent hereto as if fully set forth herein and further alleges on information and belief as follows.

40. There exist numerous statutes and regulations with respect to the manufacture and sale of pharmaceutical products which were promulgated to protect people who take prescription drugs, including Lenora Bumpus

41. By releasing the Affected Lots into the marketplace, Defendant violated these statutes and regulations and were thereby negligent per se, including the following:

a Defendant's Affected Lots were adulterated pursuant to 21 U.S.C. § 351 because, among other things, they failed to meet established performance standards, and/or the methods, facilities, or controls used for their manufacture, packing, storage or installation were not in conformity with federal requirements. See 21 U.S.C. § 351.

b Defendant's Affected Lots were adulterated pursuant to 21 U.S.C. § 351 because, among other things, their strength differs from or its quality or purity fall below the standard set forth in the official compendium for isosorbide mononitrate products and such deviation is not plainly stated on its label.

c Defendant's Affected Lots violate 21 C.F.R. § 210.1 because the process by which they were manufactured, processed, and/or held failed to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a

drug to assure that it meets the requirements as to safety and has the identity and strength and meets the quality and purity characteristics that it purposes or is represented to possess.

d Defendant's Affected Lots violate 21 C.F.R. § 211.165 because the test methods employed by Defendant were not accurate, sensitive, specific, and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented.

e Defendant's Affected Lots violate 21 C.F.R. § 211.165 in that its isosorbide mononitrate products fail to meet established standards or specifications and any other relevant quality control criteria.

f Defendant's Affected Lots violate 21 C.F.R. § 310.303 in that its isosorbide mononitrate products are not safe and effective for their intended use.

42. Defendant's negligent conduct caused substantial harm to Decedent, ultimately causing or contributing to cause her death.

43. As a direct and proximate result of the death of Lenora Bumpus, the Decedent's next of kin have suffered great losses of a personal and pecuniary nature, including loss of society, loss of consortium, loss of companionship and loss of instruction, training, advice, education and guidance, and other damages for which Defendant are liable, thus subjecting Defendant to liability under 740 ILCS 180/01, commonly referred to as the Illinois Wrongful Death Act.

PLAINTIFF DEMANDS TRIAL BY JURY ON COUNT V.

WHEREFORE, Plaintiff prays this Court enter judgment on Count V in its favor in an amount fair and reasonable to compensate the next of kin for their loss as

determined by a jury in an amount to be determined at trial in excess of $75,000, for taxable costs, post-judgment interest, and such other and further relief as this Court deems just and proper under the circumstances.

COUNT IV

Negligence Per Se – Survival Statute

COMES NOW Plaintiff Donna E. Bumpus, as Executor of the Estate of Lenora E. Bumpus, and for Count IV of Plaintiffs' Complaint against Defendant Ethex, states and allege as follows:

44. Plaintiff incorporates by reference each and every paragraph prior and subsequent hereto as if fully set forth herein and further alleges on information and belief as follows.

45. As a direct and proximate result of Defendant negligence per se with respect to its isosorbide mononitrate products as described in more detail herein, and Decedent's use thereof, Decedent Lenora Bumpus suffered serious injuries of a personal and pecuniary nature, including but not limited to, great pain and suffering prior to her death and medical expenses, subjecting the Defendant to liability pursuant to 755 ILCS 5/27-6, commonly referred to as the Illinois Survival Statute.

PLAINTIFFS DEMAND TRIAL BY JURY ON COUNT VI.

WHEREFORE, Plaintiff Donna E. Bumpus, as Executor of the Estate of Lenora E. Bumpus, prays this Court enter judgment on Count VI in her favor in an amount fair and reasonable to compensate her for her loss as determined by a jury in an amount to be determined at trial in excess of $75,000, for taxable costs, post-judgment interest, and such other and further relief as this Court deems just and proper under the circumstances.

Dated: July 7, 2010 Respectfully submitted,

CAREY, DANIS, & LOWE

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